

Ref.No.:

Mailing No.: 872663

Mailing Date: 2010/01/05 (year/month/day)

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**NOTICE OF REASONS FOR REJECTION**

**Application Number:** 2006-523496  
**Drafted:** 2009/12/24 (year/month/day)  
**Examiner:** Mina ASANO 9312 2J00  
**Attorney:** Masatake SHIGA et al.  
**Cited Articles:** Article 29, Paragraph 2

This application should be rejected for the reason(s) given below. If the applicant wishes to comment thereon, the applicant is invited to submit a response within three months from the Mailing Date of this notice.

**REASON(S)**

The inventions according to Claims 1 to 6, 8, 10, 11, 15 to 26, 29, 31 to 36, 40, and 42 to 50 of the present application could have been easily made prior to the filing of the present application by a person with average knowledge in the field to which the inventions belong based on the inventions described in the below-listed distributed publications Citations 1 to 3 or made available to the public through electric telecommunication lines in Japan or elsewhere prior to the filing of the present application, and it is therefore deemed to be unpatentable under the provisions of Japanese Patent Law, Article 29, Paragraph 2.

**EXAMINER'S COMMENTS**

**Citation 1:** PCT International Publication No. WO 00/22438

(This citation discloses the following:

Claim 10: An assay method for a prion disease, comprising the steps of: treating a sample suspected of containing a protein which assumes a first conformation and a second, disease related conformation with a compound which hydrolyzes the protein in the first conformation but not the second, disease related conformation; denaturing protein in the second, disease related conformation; contacting the treated, denatured sample with a binding partner which binds the denatured, second disease related conformation of the protein; and detecting the second, disease related conformation of the protein based on binding to the binding partner.

Lines 22 to 32 on page 4: An epitope is exposed by denaturing a disease related

conformation.)

- The first and second conformations disclosed in Citation 1 correspond to the wildtype conformation and the non-wildtype conformation of the present invention, and the hydrolyzation disclosed in Citation 1 corresponds to the step for contacting with a blocking agent of the present invention.

- The denaturation for exposing an epitope in Citation 1 corresponds to the step for modifying the candidate polypeptide to convert any inaccessible target epitope to accessible target epitope of the present invention.

- Citation 1 does not disclose a step for removing unreacted blocking agent, but a person skilled in the art could have appropriately utilized a step for removing any excess or unreacted reactant in an analysis method using a reactant in a plurality of steps.

**Citation 2:** PCT International Publication No. WO 01/06989

(In this citation, in addition to prions, various other polypeptides form aggregates and are associated with neurological disorders.)

**Citation 3:** Published Japanese Translation No. 2003-521477 of the PCT International Publication

[Citation 3': PCT International Publication No. WO 00/78344; Corresponding English language application]

(This citation discloses detecting PrP<sup>Sc</sup> within a biological sample using antibodies specific for PrP<sup>Sc</sup>.)

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## RECORD OF PRIOR ART SEARCH

• Searched Technical Fields:      IPC      G01N 33/48 – 33/98

This record of the prior art search does not constitute the reasons for rejection.

[Shiga's note regarding the labeling of publications:

"Citation" as used herein is a publication cited as grounds for denying the novelty and/or inventive step of an invention.

"Reference" as used herein is a publication that was discovered in a prior art search for determining the state of the art in the field to which the invention belongs prior to the filing of the application. A "Reference" generally does not constitute a reason for

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*rejection such as a lack of novelty and/or inventive step.*

*"Document" as used herein is a publication presented as an example showing that one or more features of an invention is a well-known technology. Ordinarily, a "Document" does not constitute a new reason for rejection but rather often substantiates an earlier finding of a lack of novelty and/or inventive step.]*